EXHIBIT 12

HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable

July 9, 2020 Tom Mirga, Editor at Large (https://340breport.com/author/tom.mirga@340breport.com/)

A note from Publisher and CEO Ted Slafsky: Attention 340B covered entities! I am honored and excited to be speaking on a virtual panel July 15 hosted by 340B Report sponsor PSG on the latest 340B developments. I am speaking with a great group of experts including my long-time colleague Bill von Oehsen of Powers Law (also a 340B Report sponsor) and Dustin Ottemiller, Vice President of Finance and Population Health at Jefferson Health. I hope you can join us for this timely and candid conversation. More details about the event and how to register can be found in PSG's sponsored content article, which is immediately after our lead story below.

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HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable

In what some perceive as a break with a position dating back to 1996, the U.S. Health Resources and Services Administration (HRSA) said late yesterday that although its 2010 contract pharmacy guidance (https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf) remains in effect, it is not legally enforceable. HRSA was

responding to questions from 340B Report about drug manufacturer Eli Lilly's July 1 decision to stop providing 340B discounts on its erectile dysfunction drug Cialis when it is dispensed by contract pharmacies.

Asked if Lilly is obligated to provide 340B-priced product to contract pharmacies, HRSA told us:

> **"Contract pharmacies are a mode for dispensing 340B drugs and serve a vital function in covered entities' ability to serve underserved and vulnerable populations. Manufacturers that refuse to honor contract pharmacy orders would have the effect of significantly limiting access to 340B discounted drugs for many underserved and vulnerable populations who may reside in geographically isolated areas and rely on a contract pharmacy as a critical point of access for obtaining their prescriptions. HRSA strongly encourages all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements.**

We asked HRSA if it would take action against Lilly for not providing 340B-priced drugs to contract pharmacies. It said:

> **"As previously stated, HRSA strongly encourages all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements.**

We also asked HRSA if it still stands by its 2010 contract pharmacy guidelines. HRSA answered:

> **“ The 2010 guidance is still in effect. However, guidance is not legally enforceable. Regarding the 340B Program’s guidance documents, HRSA’s current authority to enforce certain 340B policies contained in guidance is limited unless there is a clear violation of the 340B statute. Without comprehensive regulatory authority, HRSA is unable to develop enforceable policy that ensures clarity in program requirements across all the interdependent aspects of the 340B Program.**

When 340B Report broke the news two days ago of Lilly’s decision to stop providing 340B discounts on Cialis shipped to contract pharmacies, attorneys for health care providers interpreted the company’s move as an invitation to the U.S. Health and Human Services (HHS) Department either to sue Lilly or initiate administrative proceedings against it in defense of HRSA’s 340B contract pharmacy guidelines. It appears now that HHS and HRSA have concluded that Lilly cannot be compelled to provide 340B discounts on drugs dispensed by contract pharmacies. One attorney for providers said HRSA appears to be breaking with the position it has held on that subject for 24 years.

An attorney for drug manufacturers, however, agreed with Lilly’s position that the 340B statute imposes no obligation on manufacturers to sell to contract pharmacies at the 340B price. The government would likely fail if it tried to enforce HRSA’s non-binding contract pharmacy guidance, the attorney said.

Attorneys for providers also say HRSA’s statement to 340B Report that program guidelines are legally unenforceable could encourage other drug manufacturers to follow Lilly’s lead and declare that they, too, will stop providing 340B discounts on drugs dispensed by contract pharmacies. Depending on how many manufacturers did so, that could significantly reduce provider revenues on 340B drugs—with harmful effects, providers say, on patient care. It also could boost drug manufacturer profits.

More broadly, HRSA's statement that 340B guidance in general cannot be enforced raises questions about the viability of many 340B program requirements—not just those for manufacturers, but for covered entities, too.

According to Stephen Kuperberg, Counsel with Powers Law (https://www.powerslaw.com/practicearea/drug-pricing/), a 340B Report sponsor (https://340breport.com/why-sponsor/), when HRSA issued guidance in 1996 setting parameters for covered entities to contract with a single outside pharmacy, it "did not believe that its guidance established any new right or obligation. Rather, it interpreted the obligations established by the 340B statute in light of existing common law contract and agency law."

"Congress certainly intended for the 340B statute to be enforceable," Kuperberg continued. "That the agency has now decided it cannot act to enforce what it has maintained for over two decades was a clear and enforceable right under the statute is puzzling and disquieting, and certainly could be seen among other manufacturers as an invitation to follow suit."

Richard Church, Partner at K&L Gates, noted that when a South Carolina community health center sued HRSA in federal court in 2018 over its termination from 340B over an adverse audit finding, HRSA similarly backed down.

"Their options were similar here to either challenge Eli Lilly and risk litigation or simply encourage compliance with their guidance," Church said. "It appears they have chosen the latter path. Each of these incidents suggests that much of their guidance may not be enforceable, particularly if HRSA is unwilling to risk another litigation loss on this front."

Andrew Ruskin, also Partner at K&L Gates, added that "covered entities may opt to explore where they believe they have similar flexibilities in interpreting HRSA's guidance. That is, unless and until HRSA does get rulemaking authority from Congress."

Todd Nova, a Shareholder in Hall Render, said, "Much like with the 340B mega-guidance that was withdrawn, it seems HRSA OPA [Office of Pharmacy Affairs] is acknowledging that they do not have direct statutory guidance conferring authority to establish regulations governing contract pharmacy arrangements. Still, it is common for agencies across the HHS spectrum including OPA to publish sub-

regulatory guidance that provides insight into their interpretation of existing statutory authority. Though it's somewhat subjective, at some point that guidance becomes 'longstanding' and can be afforded the force of law by a court. The 2010 contract pharmacy guidance has been in place for quite some time now, so I do not think HRSA OPA is suggesting it is unenforceable but rather is acknowledging it is sub-regulatory rather than an authorized regulation."

Jason Reddish, Partner at Feldesman Tucker, said, "HRSA clearly continues to believe in the contract pharmacy model and rightly supports that covered entities have the well-settled ability to contract with a pharmacy to dispense the 340B drugs that they have a right to purchase. The contract pharmacy guidance is simply that—guidance for entities that choose to use a contract pharmacy so they can do so in a manner that prevents diversion and fee-for-service Medicaid duplicate discounts."

John Shakow, a Partner at King & Spalding who represents drug manufacturers, said, "The law doesn't impose any obligation on manufacturers to sell to contract pharmacies at the 340B price, so in that respect Lilly is well within its rights. Manufacturers also aren't obliged to cause product purchased by a covered entity to be shipped to anyone other than the covered entity itself (with certain exceptions). Because there is no legal obligation on manufacturers to honor contract pharmacy arrangements in this way, any attempt by the government to enforce HRSA's non-binding guidance would likely fail."

With the impact of the current public health emergency still affecting covered entities from coast to coast, this virtual version of our bi-annual event promises to provide expert perspective on all the latest developments in the 340B Program. Hosted by Jeff Spencer of PSG, this event will feature:

- Ted Slafsky, Publisher and CEO of 340B Report
- Bill von Oehsen, Principal, Powers Law
- Dustin Ottemiller, Vice President, Finance, Thomas Jefferson University Hospital
- Plus a surprise guest or two!

The conversation will cover timely topics specific to today's environment, such as:

- Eli Lilly's decision on contract pharmacy and its implications
- The status of 340B legislation, including a new bill in Congress to protect covered entity eligibility
- The latest Medicare Part B developments and impact
- How telehealth and GPO practices may be forever affected by COVID-19 public health emergency measures
- Best practices in response to the changing patient definition
- What's next for the 340B Program?

This event is for 340B covered entities only.

Wednesday, July 15, 2020 | 12:00 p.m. CST

Providers Worry About Impact if Other Drug Companies Follow Lilly's Lead on Contract Pharmacy

Corporate and pharmacy executives at 340B covered entities are concerned about the potential long-term implications for patient care and their finances of Eli Lilly and Co.'s position that there is no statutory obligation to provide 340B-priced drugs to contract pharmacies.

Hudson Headwaters Health Network, a system of 19 health centers in upstate New York, pioneered 340B multiple contract pharmacy starting in 2001 under a U.S. Health Resources and Services Administration (HRSA) demonstration project. It has

since launched a consulting firm, Hudson Headwaters 340B (https://www.hudson340b.com/), a 340B Report sponsor (https://340breport.com/why-sponsor/).

According to Hudson Headwaters 340B President Jim Donnelly (https://www.hudson340b.com/about-us/our-team/#jimdonnelly):

> **“ Without the network of contract pharmacies allowed by the current 340B contract pharmacy model, Hudson Headwaters would not be able to participate in this vital program. The 340B program has allowed Hudson Headwaters to improve medication affordability for patients with financial need through increasing discounts and coordinating assistance programs and has also contributed stability which has allowed for more comprehensive services to be accessible to all patients within its diverse and sprawling geographic footprint. Reverting to the original 340B limitations on contract pharmacies would be an extraordinary step backwards for the nation’s healthcare safety-net. This would be devastating to most covered entities, their communities and patients who now rely on the access to pharmacy services and the healthcare services 340B has been instrumental in supporting.**

Michael Bonck, System Director of Clinical Pharmacy Services at CommonSpirit Health, said:

> **340B entities may not be able to provide prescriptions to the poor and underserved patient populations in our communities, our true mission to help build healthy communities. Contract pharmacies have allowed covered entities to stretch their scare resources to be able to afford taking care of the poor and underserved within our communities long term prescription needs. It could lead to sicker populations, increased ER visits and hospitalizations, a vicious cycle. Removing contract pharmacy benefits could lead to closure not only of services, but closure of system pharmacies and in some poorer communities, even hospitals.**

A 340B program manager for a major U.S. health system who requested anonymity said:

> **Our biggest concern is with our at-risk diabetic patients who depend on insulin products produced by Lilly. A number of these patients have little to no financial means and depend on the 340B pricing to help make the insulin affordable on their limited incomes. Losing 340B pricing on those products, in particular, will shift the cost of care back to the hospital to help support these patients, causing additional financial strain onto our hospitals and health system.**

New Drug Manufacturer Notices on HRSA Website

The U.S. Health Resources and Services Administration (HRSA) has posted a new drug manufacturer notice on its website about refunds for 340B overcharges and two new manufacturer notices about limits on distribution of certain drugs.

- Spectrum Pharmaceuticals has restated its 340B ceiling price on Zevalin injection, which is used to treat non-Hodgkin's lymphoma, from Q3 2009 through Q2 2020. The notice (https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/notice-price-adjustment-spectrum.pdf) includes instruction on how covered entities may request refunds.
- Kyowa Kirin says in a notice (https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-limited-distribution-nourianz.pdf) that it has arranged for its Parkinson's disease drug Nourianz to be available for purchase at its 340B price from Cardinal Health. Covered entities also can obtain Nourianz from Caremark and Walgreens specialty pharmacies if they have a contract pharmacy relationship with such pharmacies.
- Johnson & Johnson subsidiary Actelion published a limited distribution notice (https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/limited-distribution-notice-actelion.pdf) for six products: for Opsumit, Tracleer, Uptravi, Veletri, and Ventavis (all treatments for pulmonary arterial hypertension) and for Zavesca (for Gaucher disease). 340B covered entities can access 340B ceiling prices for these products through contract pharmacy arrangements with Accredo Specialty Pharmacy. Orders must be placed with CuraScript Specialty Distribution. CuraScript will facilitate bill to/ship to replenishment orders for the products at the 340B ceiling price. Covered entities will be charged the 340B ceiling price, and product will be shipped to Accredo Specialty Pharmacy.